



September 13, 2001

WARNING LETTER NO. 2001-NOL-55

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. W. Dale Saulters, Hospital Administrator
Winston Medical Center
562 East Main Street
Louisville, Mississippi 39339

Dear Mr. Saulters:

A representative of the State of Mississippi, acting on behalf of the U.S. Food and Drug Administration (FDA), inspected your facility on August 14, 2001. This inspection revealed serious regulatory problems involving mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Processor quality control records in the month of November 2000 were missing for at least 30% of the operating days for the [REDACTED]
- Processor quality control records were missing at least 5 consecutive days for the [REDACTED]
- Phantom quality control records were missing for at least 4 weeks for unit 2, [REDACTED]

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems have been identified as Level 1, because it identifies a failure to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in

FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- **Corrective actions for processor quality control failures were not documented at least once for the [REDACTED].**

During the inspection, it was determined that there was a serious lapse in quality control from August 5, 2000 to December 10, 2000. To ensure that patient care was not jeopardized during this period, you may consider reviewing the clinical images for patients receiving mammograms between August 5, 2000 and December 10, 2000.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** the violation noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations; and,
- include sample records that demonstrate proper record keeping procedures, if the findings relate to quality control (Phantom QC, Processor QC).

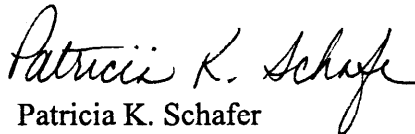
Please submit your response to:

Mark W. Rivero, Compliance Officer
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Stacy G. Marshall, MQSA Auditor, at (504) 253-4554.

Sincerely,

A handwritten signature in black ink, reading "Patricia K. Schafer". The signature is fluid and cursive, with the first name "Patricia" being the most prominent.

Patricia K. Schafer
Acting District Director
New Orleans District Office

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
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